

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

CARLOS PÉREZ-COTAPOS UGARTE,
MARIA ISABEL URETA BAZÁN,
CARLOS PÉREZ-COTAPOS
SUBERCASEAUX, INVERSIONES ANE
MIREN LIMITADA, SHERYL GROVE, and
HOORIEH ALAGHEMAND, Individually
and on Behalf of All Others Similarly
Situated,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., REMI
BARBIER, RICHARD JON BARRY,
LINDSAY BURNS, JAMES W. KUPIEC,
and ERIC SCHOEN,

Defendants.

Case No. 1:24-CV-1525-DAE

**PLAINTIFFS' OPPOSITION TO DEFENDANTS CASSAVA SCIENCES, INC.'S,
RICHARD JON BARRY'S, JAMES W. KUPIEC'S, AND ERIC J. SCHOEN'S MOTION
TO DISMISS PLAINTIFFS' AMENDED COMPLAINT**

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Plaintiffs¹ submit this memorandum of law in opposition to the Motion to Dismiss filed by Defendants Cassava, Barry, Kupiec, and Schoen (collectively, the “Company Defendants,” and together with Defendants Burns and Barbier, “Defendants”).

STATEMENT OF FACTS

This action follows years of controversy surrounding the development of Cassava’s sole therapeutic drug candidate, simufilam (formerly known as PTI-125). ¶¶2, 4. In 2021, Cassava’s longtime consultant, Dr. Wang of CUNY, who performed the final analysis for the Phase 2b Study, was accused of research misconduct and data manipulation in a Citizen Petition. ¶¶4-5. That alleged misconduct is the subject of another case pending before this Court, *In re Cassava Sciences, Inc. Sec. Litigation*, No. 1:21-cv-000751 (W.D. Tex.).

The Class Period begins the day after the CUNY Report, detailing CUNY’s investigation of Dr. Wang, was leaked to the public on October 12, 2023. ¶79. The CUNY Report indicated that the investigatory committee “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang for 14 of the 31 allegations,” including, *inter alia*, “image aberrations that may be consistent with the fabrication/manipulation of data,” and found “long-standing and egregious misconduct in data management and record keeping” and that Burns bore some responsibility for the alleged misconduct. *Id.* However, Dr. Wang’s failure to provide “underlying, original data or research records” impeded the committee’s ability to assess the merits of the allegations. *Id.*

That same day, Cassava released a statement disputing the validity of the CUNY Report. ¶¶80, 123. Defendants thereafter continued to mislead investors by downplaying the allegations of research misconduct and related investigations, and touting the controversial Phase 2b Study

¹ Unless otherwise indicated herein, capitalized terms have the same meaning as in the Amended Complaint (ECF No. 49) (the “AC”) (cited as “¶_”), emphasis is added, and internal quotation marks and citations are omitted. The Company Defendants’ brief (ECF No. 70) is cited as “Br.”

results to make simufilam's prospects appear more favorable. ¶¶125, 127, 129-30, 132, 134-35. However, unbeknownst to investors, Defendants knew, or were severely reckless in not knowing, there was support for the allegations of research misconduct. In 2022, Cassava audited Dr. Wang's laboratory related to his work on the Phase 2b Study and found it "unacceptable and temporarily not qualified to provide biomarker analysis and research for services for any future Cassava studies." ¶78. Burns also emailed Dr. Wang on May 14, 2020 sufficient information to unblind himself as to some Phase 2b Study participants before he conducted the final analysis and she removed a large portion of patients in reported cognition data (which showed no meaningful improvement in cognition) after she was unblinded. ¶84.

The truth began to trickle out on June 28, 2024, when Dr. Wang was indicted for "fabricat[ing] and falsify[ing] data in grant applications" on behalf of Cassava, causing Cassava's stock to fall about 34.83% from June 27 to June 28, 2024. ¶¶138-39. The following business day, Cassava revealed the DOJ and SEC had been investigating Cassava and "two senior employees," the Board had formed an Ad Hoc Investigation Committee to investigate, and that committee had determined that an email sent "by a senior employee of Cassava to Dr. Wang" enabled him to unblind himself. ¶¶140-41. Upon this news, Cassava's stock fell further between June 28 and July 1, 2024, from a close of \$12.35 per share to \$12.14. ¶142. Analysts reacted negatively. ¶¶241-42.

Defendants, nevertheless, continued to mislead investors, announcing on July 17, 2024 that Barbier had resigned "Other than For Cause" and not as a "result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices" and that Burns and Cassava had agreed she would "step down from her employment . . . effective immediately," but would continue to "furnish consulting services" for one year. ¶145. Barry, who took over as principal executive officer, touted Cassava's commitment to "transparency, accountability, and

highest ethical business practices,” while concealing that Burns’ and Barbier’s departures stemmed from their involvement in the research misconduct. ¶¶147-48.

The truth continued to emerge on August 8, 2024, when Cassava revealed it was in “advanced stages of discussions” with the SEC and had set aside \$40 million for potential settlement. ¶149. Cassava also informed investors not to place “undue reliance” on the Phase 2b Study results because there was “substantial uncertainty about [its] validity” based on the fact that Dr. Wang could have been unblinded and the allegations in his indictment. ¶151. Upon this news, Cassava’s stock declined about 13.84% from August 7 to August 8, 2024. ¶152. On September 26, 2024, the truth that Burns and Barbier were the senior employees under investigation, that Burns enabled Dr. Wang to unblind himself, and that Burns and Barbier could not have continued in their positions because they agreed to officer and director bars emerged when the SEC’s complaint against, and settlement with Cassava, Barbier, and Burns, became public. ¶¶153-55. Following this news, Cassava’s stock declined roughly 10.61% from September 26 to 27, 2024. ¶157.

Meanwhile, Cassava had continued to move forward with two Phase 3 clinical trials and released the topline results for the Phase 2 Study on February 7, 2024. ¶¶90-99. Defendants touted the Phase 2 Study results in the months after as “remarkable” and “unlike any Alzheimer’s trial ever” insofar as they purportedly showed no cognition decline. ¶¶160, 162-64, 166, 168, 171, 173, 175. However, Defendants had skewed the data, such that the results only analyzed roughly 53% of the intent-to-treat population (*i.e.*, all randomized patients, regardless of treatment) (“ITT”). ¶¶29, 102. They misled investors about the patient population analyzed, disclosing that the Full Analysis Set (“FAS”) consisted of “all study participants who received at least one dose of treatment and ha[d] both baseline and at least one post-baseline assessment,” whereas the final Phase 2 Study results later published on ClinicalTrials.gov on February 12, 2025 revealed that the

actual FAS population analyzed consisted of “those patients who completed an ADAS-Cog-11 assessment at baseline and month 24.” ¶¶102, 106. Thus, patients who either dropped out of the study before the end or were unavailable at the end were not included in the analysis. ¶106. This change was significant because the results may have been biased towards patients who were, or were perceived to be, benefitting from treatment, and the revised analysis violated ICH E9 standards, which guide the analysis of clinical trials and are the FDA’s official policy. ¶¶104, 107-09. It also differed significantly from the analysis utilized in the later Phase 3 clinical trials (ITT analysis, which included *all* randomized patients), such that, unbeknownst to investors, there were limitations in how well the Phase 2 Study might predict the Phase 3 trial results. ¶110. Moreover, the Phase 2 Study results (even with the limited patient population analyzed) were not as remarkable as Defendants made them seem. ¶¶111-12, 114.

The previously undisclosed risk that the Phase 2 Study results were not supportive of simufilam’s potential (due to the limitations discussed above) began to materialize on November 25, 2024, when Cassava announced that simufilam failed to meet the pre-specified endpoints in the Phase 3 RETHINK-ALZ study and that Cassava was therefore discontinuing the Phase 3 REFOCUS-ALZ study. ¶119. Cassava’s stock declined roughly over 83% from November 22 to November 25, 2024. ¶183. The risk continued to materialize on March 25, 2025, when Cassava announced that simufilam also failed the Phase 3 REFOCUS-ALZ study, and Cassava’s stock declined over 32% from March 24 to March 25, 2025. ¶¶121, 191. In response, H.C. Wainwright downgraded Cassava to “Neutral” and expressed surprise about the Phase 3 results, given the promising Phase 2 Study results. ¶249.

Defendants were motivated to mislead investors because Cassava did not generate any revenue and its business was entirely dependent on the successful development of simufilam for

commercial sale. Accordingly, Cassava needed to raise additional capital necessary for the drug's continued development. ¶116. To do so, Cassava misled investors about simufilam's prospects and distributed warrants to shareholders, raising gross proceeds of approximately \$21.8 million between January 3, 2024 and February 26, 2024. ¶117.

LEGAL STANDARD

The Court must “accept all well-pleaded facts as true and draw all reasonable inferences in favor of the plaintiff.” *BG Gulf Coast LNG, L.L.C. v. Sabine-Neches Navigation Dist.*, 49 F.4th 420, 425 (5th Cir. 2022). To state a Section 10(b) claim, the AC must allege: “(1) a material misrepresentation or omission; (2) scienter (a wrongful state of mind); (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) a causal connection between the material misrepresentation and the loss.” *Okla. Firefighters Pension & Ret. Sys. v. Six Flags Ent. Corp.*, 58 F.4th 195, 206 (5th Cir. 2023) (“*Six Flags*”).

ARGUMENTS

I. THE AC ALLEGES ACTIONABLE MISSTATEMENTS.

A. The Tainted Phase 2b Study and the Investigations Related Thereto (¶¶123, 125, 127, 129-30, 132, 134-35) Are Actionable.

The Company Defendants argue the response to the CUNY Report and statements regarding the government investigations and internal investigation (¶¶123, 125, 127, 129-30, 132) are inactionable because each statement was technically true. Br. at 11. As this Court previously recognized, “it is well-settled that ‘the ability of a statement to provide accurate information, rather than the statement’s literal truth, is the benchmark by which statements to the market are measured in securities fraud cases.’” *In re Cassava Scis., Inc. Sec. Litig.*, 2023 WL 3442087, at *8 (W.D. Tex. May 11, 2023) (Ezra, J.). As discussed below, each of these statements, irrespective of whether they were literally true, misled investors.

1. Defendants' Response to the CUNY Report Was Misleading.

Defendants' response to the CUNY Report undermined its validity and misleadingly suggested that the allegations of research misconduct—including that Burns bore some responsibility—were baseless by highlighting that the report “makes no findings of data manipulation” and “the egregious misconduct . . . relates exclusively to internal record-keeping failures at CUNY.” ¶123. This was misleading because Defendants knew, or recklessly disregarded, evidence substantiating the CUNY Report allegations. Specifically, Cassava had already audited Dr. Wang's laboratory related to the Phase 2b Study and made similar findings: the laboratory “lack[ed] standard operating procedures, proper good documentation practices, and laboratory practices (*i.e.*, equipment calibration and sample management) that are deemed critical for conducting any type of analysis to support a critical trial,” rendering it “unacceptable and temporarily not qualified to provide biomarker analysis and research services for any future Cassava studies.” ¶12; ECF No. 68-3 at 7.² Burns also had emailed Dr. Wang sufficient information to unblind himself and removed a large portion of patients in reported cognition data (which showed no meaningful improvement in cognition) after she was unblinded. ¶124.

The Company Defendants argue the response was not misleading because investors could compare the publicly available CUNY Report with Defendants' response. Br. at 12. However, a comparison would not reveal this concealed information that rendered the response misleading.³ They also are incorrect that Defendants' statement that CUNY had “no legitimate basis” on which to make accusations of research misconduct is an inactionable opinion. Br. at 12. A statement of

² While the Audit Report is referenced in the AC, as detailed in the motion to strike, Defendants cannot use it to inject their own conflicting version of the facts.

³ The Company Defendants' authority (Br. at 15) is inapposite because the information rendering the statements misleading in those cases was public. *See Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004) (gas price trends publicly available); *Greenberg v. Crossroads Sys., Inc.*, 364 F.3d 657, 670 (5th Cir. 2004) (misleading information previously “released to the market”).

opinion does not “express[] certainty about a thing,” whereas a statement of fact does. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund.*, 575 U.S. 175, 183 (2015). Here, Defendants expressed certainty that there was no basis for the accusations of research misconduct when there was.⁴ Regardless, even assuming *arguendo* it is an opinion, it still is actionable because Defendants could not have sincerely held that belief as it did not “fairly align[] with the information in [their] possession at the time” (*i.e.*, Cassava’s audit of Dr. Wang’s laboratory and Burns’ involvement in the research misconduct). *Omnicare*, 575 U.S. at 189.

2. Defendants Misled Investors About the Government Investigations.

The Company Defendants argue Defendants did not have a duty to disclose anything with respect to the government investigations beyond what they did. Br. at 13. However, Defendants had a duty to “speak the full truth” and “to disclose a mix of information that is not misleading” when they spoke on the topic. *Six Flags*, 58 F.4th at 217; *see also In re ArthroCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 716 (W.D. Tex. 2010) (defendants not “obligated to respond to every potentially disparaging news story, but once they [took] it upon themselves to respond . . . , they were required to speak the full truth and accurately inform, rather than mislead, investors”).

Here, they failed to do so. Their statements that “[n]o government agency” informed Cassava that it “found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors” (¶¶125, 127) were misleading because a reasonable investor would have been led to believe that there was no evidence of research misconduct. That was not the case, as Defendants knew or recklessly disregarded the evidence supporting the accusations of research misconduct. *See* ¶128; *Supra* Section II.A.1.⁵

⁴ Thus, Defendants’ authority, *Southland Sec. Corp. v. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 372 (5th Cir. 2004), which contained “no concrete factual . . . misrepresentation,” is inapposite.

⁵ The Company Defendants’ authority (Br. at 13) is inapposite. *See Ind. Elec. Workers’ Pension Tr. Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 541-42 (5th Cir. 2008) (no affirmative duty to

3. Defendants Misled Investors About the Orrick Investigation.

“[C]ontext is instrumental in determining whether a statement is misleading.” *Stone v. Life Partners Holdings, Inc.*, 26 F. Supp. 3d 575, 595 (W.D. Tex. 2014). Defendants’ statements about the Orrick investigation were misleading in context insofar as they disclosed the allegations that “the Company and certain of its employees and third-party collaborators had engaged in research misconduct in connection with the development of simufilam,” and in the next paragraph, stated that Cassava’s Board had retained Orrick to “investigate these allegations.” ¶129.⁶ Defendants then stated that the investigation “found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct,” omitting third-party collaborators. ¶¶129-30. A reasonable investor, viewing the statement in context, would be misled that there was no evidence to substantiate the allegations of research misconduct when Defendants knew or should have known that was not the case. ¶131.

The Company Defendants fail to dispute that this statement was false or misleading based on Burns’ involvement in the research misconduct. ¶131. Further, contrary to the Company Defendants’ assertion otherwise (Br. at 13-14), the AC disputes that Orrick could have possibly found no evidence of research misconduct, given that the investigation was on the heels of the widely publicized accusations of research misconduct; Orrick had access to “Company personnel, communications, documents, data, and information” and “technical experts with relevant experience and knowledge”; and Cassava possessed evidence substantiating the accusations of research misconduct (¶¶129, 205). Any reasonable investigation would have uncovered that

disclose where omission “did not make its announcement untrue or misleading”); *R2 Invs. LDC v. Phillips*, 401 F.3d 638, 644-45 (5th Cir. 2005) (analyzing scienter, not whether the statements were misleading); *Gambrill v. CS Disco, Inc.*, 2025 WL 388828, at *5-6 (W.D. Tex. Jan. 30, 2025) (prospectus adequately warned of what plaintiffs alleged was misleading).

⁶ Thus, Defendants’ own disclosure contradicts the Company Defendants’ suggestion that the scope of the investigation did not include third parties like Dr. Wang. Br. at 13-14.

evidence unless Orrick was actively misled. Regardless of what Orrick concluded, *Defendants knew about, or recklessly disregarded* the evidence substantiating the accusations, and thus their statements were misleading for the same reasons discussed *supra* Section I.A.2.

4. The Statements Touting the Phase 2b Study Results Were Misleading.

Defendants also misled investors by continuing to tout the Phase 2b Study results (§§134-35) notwithstanding the extensive investigations into accusations of research misconduct during the Phase 2b Study and the evidence substantiating the accusations (§136). The Company Defendants appear to contend that they cannot be held liable for “accurately summarizing historical results.” Br. at 14. This argument fails because continuing to tout historical results while being aware of evidence calling into question the reliability of those results (*i.e.*, the evidence substantiating that research misconduct occurred during the Phase 2b Study) is misleading. *See Cohen v. Kitov Pharms. Holdings, Ltd.*, 2018 WL 1406619, at *5 (S.D.N.Y. Mar. 20, 2018) (complaint adequately alleged material omissions where defendants touted study results “but failed to disclose that the results had been falsified”); *Sanders v. AVEO Pharms., Inc.*, 2015 WL 1276824, at *8 (D. Mass. Mar. 20, 2015) (“Making misleading statements as to a drug’s efficacy by relying on results of a trial conducted with methodological errors is . . . actionable.”). The Company Defendants’ authority (Br. at 14) does not support otherwise, as none of their cases involved situations where defendants continued to tout historical results *after* information came to light that rendered their continued reliance on those results questionable.⁷

⁷ *See Nathenson v. Zonagen Inc.*, 267 F.3d 400, 419 (5th Cir. 2001) (failing to adequately plead how purported fundamental flaws in trial methodology rendered general statements about positive results misleading); *Kapps*, 379 F.3d at 211-12 (upholding dismissal of allegations that increasing gas prices over a period were misleading because of failure to disclose drop in gas prices during a portion of that period); *McCloskey v. Match Grp., Inc.*, 2018 WL 4053362, at *4 (N.D. Tex. Aug. 24, 2018) (statements accurately reporting historical performance that made no projections about future performance not misleading).

The Company Defendants, seemingly relying on a truth-on-the-market defense, also contend they should escape liability for their misstatements about the Phase 2b Study controversy because it was already publicized prior to the Class Period. Br. at 14-15. “To establish such a defense, a defendant must show that the material negative information that he did not disclose was transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created” *In re Sec. Litig. BMC Software, Inc.*, 183 F. Supp. 2d 860, 906 (S.D. Tex. 2001). This is “intensely fact-specific and is rarely an appropriate basis for dismissing a §10(b) complaint.” *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000); *Carmignac Gestion, S.A. v. Perrigo Co. PLC*, 2019 WL 3451523, at *9 (D.N.J. July 31, 2019) (“At the motion to dismiss stage, a defendant must establish the truth on the market defense as a matter of law on the basis of the allegations in the complaint in order to warrant dismissal.”).

A truth-on-the-market defense is especially inappropriate under these facts because Defendants repeatedly tried to discredit the allegations of research misconduct. ¶¶123, 125, 127, 129-30, 132. *See Klein v. Altria Grp., Inc.*, 525 F. Supp. 3d 638, 664 (E.D. Va. 2021) (“[I]n light of Defendants’ affirmative denial of the information available to the market, weighing the intensity and credibility of the transmission of the information to the public to determine if it counterbalances the impression created by Defendants’ statements makes the Court’s task even more fact-intensive and inappropriate for a motion to dismiss.”).

B. The Statements Regarding the Phase 2 Study Results (¶¶160, 162-64, 166, 168, 171, 173, 175) Are Actionable.

Defendants’ Statements about the Phase 2 Study results were misleading because Defendants failed to disclose that the results were skewed because they analyzed only 53% of the ITT population, and, in violation of ICH E9 principles, did not include patients who were unavailable at the end of the study or dropped out before completion (subjecting the results to

potential bias). ¶¶102, 106-09.⁸

The Company Defendants’ argument that the “the core factual” statements Defendants made were accurate (Br. at 15) misses the mark for the same reasons discussed *supra* Section I.A. Similarly, the Company Defendants are incorrect that Defendants accurately disclosed the relevant analysis sets and methodology. Br. at 16. First, they ignore Defendants’ misleading disclosure that the patient population analyzed for the Phase 2 Study included “all study participants who received at least one dose of treatment **and have both baseline and at least one post-baseline assessment**,” when the final results later revealed that the actual patient population analyzed was different: “those patients who completed an ADAS-Cog-11 assessment at baseline **and month 24**.” ¶¶103, 106. While Defendants attempt to deflect by framing ICH E9 principles as a “preferred” method (Br. at 16), the AC plainly alleges they are the FDA’s “official policy” (¶104). Even if compliance were optional, the statements about the patient population analyzed would still be misleading.

Because of Defendants’ manipulations, the Phase 2 Study results were not an adequate indicator of simufilam’s true prospects. Disclosing that the analysis sets might differ between the studies (Br. at 16), especially given the substantial differences between the analysis methods used, did not make their statements not misleading. Further, contrary to the Company Defendants’ suggestion (Br. at 17-18), Plaintiffs do not contend that Defendants had a duty to compare the predictive value of the Phase 2 Study results to potential Phase 3 outcomes.⁹ Rather, Defendants’

⁸ The Company Defendants’ authority is therefore inapposite. *See Nathenson*, 267 F.3d at 419 (challenging results as unreliable due to flaws in the study, not misleading skewing of the results).

⁹ The Company Defendants’ authority, *R2*, 401 F.3d at 642, which involved statements about tender offer obligations that were allegedly misleading because the company did not have sufficient cash on hand to make the payments, fails to support that “Companies are not required to preface accurate reports of current data with speculative analyses of future trial designs.” Br. at 17. Further, simply because *Nathenson*, 267 F.3d at 404, summarized what happens during clinical trials does not mean that such differences are “well understood,” Br. at 17, especially where, like here, Defendants misrepresent aspects of it.

misleading statements *prevented investors* from assessing how simufilam was likely to perform in the Phase 3 trials. ¶¶31, 110.

In addition, the February 7, 2024 press release’s reference to “n=47,” “n=40,” and “n=32” did not adequately inform investors that the Phase 2 Study results only analyzed roughly 53% of the ITT population. *See Alberici v. Recro Pharma, Inc.*, 2020 WL 806719, at *12 (E.D. Pa. Feb. 14, 2020) (“[A] reasonable investor cannot be expected to understand complex medical data.”). Even assuming a reasonable investor would have understood from that disclosure that a significant portion of the patient population was not included in the analysis, it was nonetheless misleading for Defendants to tout the study results without qualifying that they had limited probative value due to the smaller population analyzed. ¶¶168, 171, 173. *See also Perrigo*, 2019 WL 3451523, at *10 (claims of being “insulated from the current pricing drama” were misleading for not disclosing qualifying information about increased competition in the generic market).

Further, warning about hypothetical study limitations does not foreclose liability for misleading investors about *existing* limitations that rendered the Phase 2 Study results not as remarkable and supportive of simufilam’s potential as Defendants led investors to believe. *See Ga. Firefighters’ Pension Fund v. Andarko Petrol. Corp.*, 514 F. Supp. 3d 942, 953 (S.D. Tex. 2021) (“When risks have already begun to materialize, it is no longer sufficient to generally warn of the possibility of these risks in the future.”). The Company Defendants’ authority (Br. at 17) is inapposite. *See Omnicare*, 575 U.S. at 189-94 (analyzing when omissions render *opinion* statements misleading); *Rubinstein v. Collins*, 20 F.3d 160, 167 (5th Cir. 1994) (involving forward-looking forecasts and predictions “couched in cautionary language”).¹⁰

¹⁰ Defendants also fail to explain why the misstatements are opinions or why the bespeaks caution doctrine would shield Defendants from liability, such that *Omnicare* and *Rubinstein* would apply

In addition, the Company Defendants’ arguments that certain statements are non-actionable puffery (Br. at 17) fall flat. “[O]nly statements that contain no concrete factual or material misrepresentation may be deemed puffery.” *In re SolarWinds Corp. Sec. Litig.*, 595 F. Supp. 3d 573, 587 (W.D. Tex. 2022), *clarified on other grounds*, 2022 WL 3699429 (W.D. Tex. Aug. 19, 2022). *See also Carlton v. Cannon*, 184 F. Supp. 3d 428, 494 (S.D. Tex. 2016) (a statement that is “objectively verifiable” is not puffery), *R. & R. adopted*, 2016 WL 3959164 (S.D. Tex. July 22, 2016). Defendants excise words and phrases, ignoring their broader, objectively verifiable context (reflected in bold): “Those results were unlike any Alzheimer’s trial ever, **reporting stable cognition for two full years in Alzheimer’s disease patients with mild dementia**”; “[T]he data from the [Phase 2 Study] was remarkable **in that patients with mild dementia apparently had no significant decline during that two-year treatment period**”; and “[W]hat was persuasive about [the Phase 2 trial], at least to me, was that the uh – at the end of [the] 2 years the mild patients in the trial showed virtually no cognition decline. I mean that is unheard of.” ¶¶168, 171, 173. These statements about cognition decline are all objectively verifiable and thus actionable. Defendants’ authority (Br. at 17) is distinguishable. *See Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 869 (5th Cir. 2003) (involving “generalized, positive statements about the company’s competitive strengths, experienced management, and future prospects”); *Southland*, 365 F.3d at 372 (“vague and optimistic” statements that “contain no concrete factual or material misrepresentation”).

C. Defendants Misled Investors About Barbier’s and Burns’ Departures (¶145).

The AC plausibly alleges Defendants misled investors about the reason behind Barbier’s and Burns’ departures (their involvement in the Phase 2b Study controversy). ¶¶145, 148. On July

and “[a]rguments that are insufficiently addressed in the body of the brief . . . are waived.” *Maldonado v. GEO Grp., Inc.*, 2020 WL 10357002, at *4 (W.D. Tex. Dec. 16, 2020).

1, 2024, Cassava announced the DOJ and SEC were investigating “two senior employees of the Company” and sixteen days later, Cassava announced Burns’ and Barbier’s departures. ¶¶140, 145. Less than a month later, Cassava was already in “*advanced stages of [settlement] discussions* with the SEC.” ¶149. The SEC ultimately charged Burns and Barbier, and as part of their settlement, they agreed to officer-and-director bars. ¶155. The timing of these disclosures supports the inference that when Barbier and Burns departed Cassava, Defendants knew details regarding the SEC’s investigation of them and were already discussing the potential terms of the settlement, including that Barbier and Burns would be barred from serving as officers and directors. Defendants tried to anticipatorily take the sting out of this announcement by controlling the narrative around their departures before the truth became public.

The Company Defendants challenge the Barbier disclosure as “accurately reflect[ing] the contractual characterization and the standard disclosure language used to comply with Item 5.02(a)(2).” Br. at 18. They fail to support that Item 5.02(a)(2) excuses Defendants from accurately reporting why Barbier left Cassava. They also suggest Defendants were not obligated to provide more detail about Burns’ and Barbier’s departures. *Id.*¹¹ Yet, Defendants failed to comply with their duty to “speak the full truth” and “to disclose a mix of information that is not misleading” once they chose to speak about Barbier’s and Burns’ departures. *Six Flags*, 58 F.4th at 217.

D. The Statement About Cassava’s Commitment to Transparency (¶147) is Actionable.

Defendants also misled investors by touting Cassava’s purported commitment to

¹¹ The Company Defendants’ authority lends no support. See *Firefighters Pension & Relief Fund of the City of New Orleans v. Bulmahn*, 147 F. Supp. 3d 493, 536 (E.D. La. 2015) (announcement of resignation *accurately explained* the reason: “disagreement between [him] and [the Company’s] management”), *aff’d sub nom. Neiman v. Bulmahn*, 854 F.3d 741, 752 (5th Cir. 2017) (no allegations that the defendants “knew or were reckless in not knowing [the executive’s] ‘true’ reasons” for resigning).

transparency because they masked the research misconduct and Company executives' involvement in it. ¶¶147-48. Defendants make the conclusory argument that the statement amounts to “non-actionable corporate puffery,” citing two cases without any parenthetical explanations as to why they believe those cases support their conclusory argument, asking Plaintiffs and the Court to make the analytical leaps for them. Br. at 18.¹² That alone is a basis for rejecting their argument. *See Coury v. Moss*, 529 F.3d 579, 587 (5th Cir. 2008) (estoppel argument waived where defendants cited cases but failed “to explain how [the] cases constitute[d] authority for their bare assertion that Coury [was] estopped to bring this litigation”); *Delgado v. McHugh*, 2011 WL 11741023, at *1 n.1 (W.D. Tex. Nov. 21, 2011) (criticizing lack of “parenthetical explanations for citations” and “Counsel’s assumption that it is incumbent upon the Court to excavate evidence from the record in order to tie legally-redressable claims together with binding legal authority,” which “belies the Court’s role as a neutral arbiter”).

Regardless, the Company Defendants’ authority is distinguishable because unlike here, those cases involved “generalized, positive statements about the company’s competitive strengths, experienced management, and future prospects.” *Southland*, 365 F.3d at 372; *Rosenzweig*, 332 F.3d at 869.

II. THE AC ALLEGES A STRONG INFERENCE OF SCIENTER.

“A complaint adequately pleads scienter by alleging facts that support the defendant acted with an intent to deceive, manipulate, or defraud or severe recklessness.” *Six Flags*, 58 F.4th at 214. “The inquiry is whether all of the facts alleged, taken collectively, give rise to a strong plausible inference of scienter, not whether any individual allegation, scrutinized in isolation,

¹² The Company Defendants’ brief is riddled with other deficient citations. *E.g.*, Br. at 13-15, 17-18, 22-23 (citing various cases without quoting them or including parenthetical explanations).

meets that standard.” *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 251 (5th Cir. 2009). “The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences.” *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). “[A] tie favors the plaintiff on a motion to dismiss.” *Six Flags*, 58 F.4th at 214.

The Company Defendants purport to challenge scienter for all misstatements (Br. at 19-23) but fail to offer any argument with respect to the statements about Barbier’s and Burns’ departures and Cassava’s commitment to transparency (¶¶145, 147), thereby waiving it. *See Julie L. v. Kijaazi*, 2023 WL 5279171, at *3 n.6 (S.D. Tex. Aug. 16, 2023) (“Because Plaintiff does not support this conclusory argument, it is waived.”); *ADR Int’l Ltd. v. Inst. for Supply Mgmt. Inc.*, 667 F. Supp. 3d 411, 422 n.4 (S.D. Tex. 2023) (“It is not enough to merely mention or allude to a legal theory. . . . [B]ecause Defendants did not adequately brief its assertion, the Court does not address it.”).¹³ The AC adequately alleges scienter for the remaining misstatements.

A. Defendants Knew or Recklessly Disregarded Evidence Substantiating the Allegations of Research Misconduct.

The Company Defendants incorrectly argue that Defendants’ scienter rises or falls on whether they knew that Dr. Wang had manipulated the Phase 2b Study. Br. at 19. That is inconsequential. Defendants knew or should have known that their statements were misleading because they knew there was evidence substantiating the misconduct allegations (*i.e.*, Cassava’s 2022 audit of Dr. Wang’s laboratory and Burns’ involvement in the research misconduct.)¹⁴

1. Cassava’s 2022 Audit of Dr. Wang’s Laboratory Found Critical Issues.

¹³ Regardless, the AC adequately alleges scienter with respect to those misstatements. ¶¶140-41, 208-09.

¹⁴ As detailed in Plaintiffs’ Opposition to Burns’ and Barbier’s motion §II.A.3, incorporated herein by reference, Defendants also ignored significant red flags, which supports their scienter.

In 2022, over a year before the first alleged misstatement, Cassava audited Dr. Wang’s laboratory related to his work on the Phase 2b Study and found critical deficiencies. ¶¶12, 203. Burns, who was Dr. Wang’s primary point of contact, and Barbier were generally aware of the report’s findings. ¶204. Kupiec likewise knew or should have known about the audit findings because he was responsible for overseeing clinical studies then. *Id.* Schoen also knew or recklessly disregarded the audit findings because he caused Cassava to issue the response to the leaked CUNY Report and any reasonable investigation into the allegations of research misconduct to ensure the response’s accuracy would have uncovered Cassava’s audit. *Id. See also Cassava Scis.*, 2023 WL 3442087, at *9 (rapid “denials can indicate that a defendant was either sufficiently familiar with the facts, or severely reckless in not being familiar, to be in a position to issue a denial”).

The Company Defendants mischaracterize the Audit Report as focused solely on future work and not prior misconduct. Br. at 19-20. As discussed in the accompanying motion to strike, the Court should reject their attempt to use the Audit Report to improperly inject their own version of the facts. Nevertheless, the Company Defendants’ argument lacks merit because the audit was instigated by the Phase 2b Study controversy. *See* ECF No. 68-3 at 1 (identifying Audit Report’s applicable project name as “A Phase 2b, Randomized, Double-blind, Placebo-controlled, Multiple Dose, Biomarker and Safety Study of PTI-125 [(Simufilam)] in Mild-to-[M]oderate Alzheimer’s Disease Patients.”).¹⁵ Further, the conclusion that the lab was unsuitable for future work was based on *prior* conduct and practices existing during the Phase 2b Study. *See* ECF No. 68-3 at 6

¹⁵ The SEC Complaint likewise connects them. *See* ECF No. 68-6 ¶84 (“Following complaints raised in the citizen petition, the FDA performed a review of Dr. Wang’s laboratory at CUNY. Following the FDA’s review, Cassava initiated its own audit of Dr. Wang’s laboratory ***related to his work on the Phase 2b trial***. Cassava’s Senior Director of Clinical Quality Systems ***reviewed documents related to the Phase 2b trial*** and conducted a site visit to Dr. Wang’s laboratory . . .”).

(indicating that “[e]ssential equipment . . . had not been calibrated *in several years*” and that an “instrument and freezer *had not been validated/qualified prior to sample analysis and sample storage*”). These findings support that Defendants knew or should have known about issues with Dr. Wang’s laboratory related to his work on the Phase 2b Study when they misled investors about the alleged research misconduct.

2. Burns’ Involvement in the Alleged Research Misconduct.

In addition to the Audit Report, Burns’ involvement in the research misconduct—emailing Dr. Wang sufficient information to unblind himself before conducting the final Phase 2b Study analysis and removing a large portion of patients in reported cognition data (which showed no meaningful improvement in cognition) after she was unblinded (§84)—supports scienter. The Company Defendants focus solely on her email to Dr. Wang, ignoring the allegations about her personal involvement (*i.e.*, removing patients from reported cognition data). They therefore waive any arguments with respect to those allegations. *See Nestle USA, Inc. v. Ultra Distribuciones Mundiales S.A. de C.V.*, 516 F. Supp. 3d 633, 653 (W.D. Tex. 2021) (Ezra, J.) (“Arguments raised for the first time in a reply brief are generally waived . . .”). *See also Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, 66 F. Supp. 3d 795, 811 (E.D. Tex. 2014) (“Failure to raise an argument in a motion waives the argument; raising it for the first time in a reply memorandum is too late.”). Nonetheless, Burns’ involvement supports Defendants’ scienter for two reasons.

First, Burns knew about her involvement in the research misconduct when she touted the tainted Phase 2b Study results (§134), and her scienter can be imputed to Cassava. *See Lee v. Active Power, Inc.*, 296 F. Supp. 3d 876, 881 (W.D. Tex. 2014) (scienter may be imputed from employee who “makes a false statement” or “furnished information used in a false statement”).

Second, Burns presumably discussed the CUNY Report’s allegation of her involvement with her husband, Barbier (§197), and Schoen before they caused the Company to issue the

response denying it. Even if she actively misled them or they failed to ask her before issuing the response, any reasonable investigation into the allegations would have uncovered her involvement. ¶200. *See also Cassava Scis.*, 2023 WL 3442087, at *9 (rapid “denials can indicate that a defendant was either sufficiently familiar with the facts, or severely reckless in not being familiar, to be in a position to issue a denial”). Thus, Barbier and Schoen either knew or recklessly disregarded Burns’ involvement in the research misconduct, which rendered their statements regarding the tainted Phase 2b Study and related investigations false or misleading. *See id.* at *11 (“[t]he misleading nature of certain statements . . . would have been readily apparent given the importance of [the matter] to Cassava, even to someone without a science background,” supporting Schoen’s scienter).

The Company Defendants argue Burns’ email to Dr. Wang does not support scienter because the AC fails to establish that Defendants could have known the implications of the email from its face. Br. at 20-21. However, the inference that it was apparent to Defendants—individuals in the business of developing drugs through clinical trials—is at least equally as plausible, which is sufficient to plead scienter.¹⁶ The fact that the SEC provided Cassava “with new information obtained during its investigation” does not support that Defendants needed its assistance to understand the implications of the email, as the Company Defendants suggest (Br. at 20-21), especially given that Cassava’s own Ad Hoc Investigation Committee was able to determine the significance of the email (¶141). Moreover, it defies logic that Burns—the Senior Vice President of Neuroscience, who co-authored articles on the science underlying simufilam and manipulated cognition data from the same study (¶¶57, 197)—did not understand what she sent. The Company

¹⁶ Even if the Court were permitted to consider the Company Defendants’ extraneous allegation about the SEC’s purported “sophisticated post hoc analysis,” they fail to support it. Br. at 21.

Defendants’ speculation that Burns must not have understood the implications of her email because the SEC charged her with mere negligence (Br. at 21-22) ignores the host of other possibilities why the SEC might have made that strategic decision. Thus, drawing the reasonable inferences in Plaintiffs’ favor, Defendants’ fraud by hindsight argument collapses (Br. at 20-21) and Burns’ email to Dr. Wang contributes to the inference of scienter.¹⁷

B. Kupiec’s Access to and Review of Phase 2 Study Data and Kupiec’s and Barry’s Public Discussion of the Phase 2 Study Data Supports Their Scienter.

Access to study data and public discussion of it supports scienter.¹⁸ *See Reese v. Malone*, 747 F.3d 557, 574 (9th Cir. 2014) (defendant “bridged the scienter gap . . . by referencing the data directly”), *overruled on other grounds by City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 865 F.3d 605 (9th Cir. 2017); *Rensin v. U.S. Cellular Corp.*, 755 F. Supp. 3d 1048, 1065 (N.D. Ill. 2024) (“receipt of reports of key performance indicators and discussion of the same at . . . meetings” supported scienter); *Voulgaris v. Array Biopharma Inc.*, 2020 WL 8367829, at *21 (D. Colo. Nov. 24, 2020) (“Given the statements that Defendants made about the [clinical] trial and its results, . . . it is simply not plausible that Defendants did not know the results of both the positive and negative data”); *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *12 (C.D. Cal. Feb. 27, 2015) (“[I]nference of scienter . . . established by the fact that the Defendants touched on the specific issue . . . in their public statements.”).

Here, Kupiec was responsible for overseeing, monitoring, and interpreting the Phase 2

¹⁷ Defendants’ authority (Br. at 20-22) lends no support. *See Flaherty & Crumine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009) (summarizing severe recklessness standard); *Lormand*, 565 F.3d at 254 (private admissions contradicted public statements); *Shaw Grp.*, 537 F.3d at 542-43 (no allegations explaining how defendants knew information rendering their statements misleading).

¹⁸ The Company Defendants’ one-sentence argument that the reported results were accurate (Br. at 22) misses the mark for the reasons discussed *supra* Section I.B

Study while part of it was ongoing. ¶213. He therefore had access to and reviewed the data underlying it. Kupiec and Barry also publicly discussed the data. Barry touted the Phase 2 Study results as “unlike any Alzheimer’s trial ever,” stating, “I encourage you to study the cognition results,” expressed excitement about simufilam based on “what we’ve seen in biomarkers” during the Phase 2 Study, opined about the implications of some of the results, and discussed the underlying data. ¶¶168, 173, 175. Kupiec similarly discussed how “the data from the [Phase 2 Study] was remarkable.” ¶171. This contributes to the inference of their scienter.

C. Defendants’ Motive to Raise Much-Needed Capital for the Continued Development of Simufilam Supports Their Scienter.

This court has already recognized that “pumping up Cassava’s stock price” to “raise much-needed working capital for the future development of simufilam” “can be probative of scienter.” *Cassava Scis.*, 2023 WL 3442087, at *10. Here, the allegations that Defendants falsely touted simufilam’s prospects so that they could raise additional capital to pay for the continued development of simufilam (¶¶14, 116, 220-27) support scienter. The Company Defendants’ authority supports this. Br. at 22 (citing *Owens v. Jastrow*, 789 F.3d 529, 539-40 (5th Cir. 2015), which held defendants’ motive to raise capital “contribute[d] to a finding of scienter”).

D. The Core Operations Theory Bolsters the Inference of Scienter.

“[S]pecial circumstances, taken together with an officer’s position, may support a strong inference of scienter,” including: “(1) the company’s size; (2) whether the transaction at issue was critical to the company’s continued vitality; (3) whether the misrepresented information would have been readily apparent to the speaker; and (4) whether the defendant’s statements were internally consistent with one another.” *Six Flags*, 58 F.4th at 219. *See also Rougier v. Applied Optoelectronics, Inc.*, 2019 WL 6111516, at *12 (S.D. Tex. Mar. 27, 2019) (“The Fifth Circuit has held that material misstatements as to a company’s most significant asset can give rise to a strong

inference that those misstatements were made with knowledge of their falsity or severe recklessness in not knowing that they were false.”).

The Court has already concluded that the “first two circumstances are clearly present.” *Cassava Scis.*, 2023 WL 3442087, at *10. Nothing has materially changed since then. Simufilam is Cassava’s only therapeutic drug candidate and Cassava is admittedly “heavily dependent on the success of simufilam.” ¶¶230-31. Cassava is also a tiny company. *See* ¶229 (24 full-time employees in 2021, 26 in 2022, 29 in 2023, and 30 in 2024).¹⁹

The third factor is also present, as the misleading nature of Defendants’ statements would have been readily apparent to them because “[e]ach of [the] Defendants had important responsibilities at Cassava.” *Cassava Scis.*, 2023 WL 3442087, at *10 (finding the third prong satisfied with respect to Burns and Barbier on similar allegations). Kupiec was Chief Medical Officer during the Class Period and the Chief Clinical Development Officer before that. ¶195. As Chief Clinical Development Officer, he monitored clinical research, interpreted study data, led the Phase 3 clinical development strategy for simufilam, and was familiar with the discussions during the End-of-Phase 2 meeting with the FDA, which he commented on in a press release. *Id.* As discussed *supra* Section II.B, Kupiec also reviewed the data related to the Phase 2 Study and monitored patient data as Chief Medical Officer. ¶214. Barbier, on whom Cassava admitted it heavily relied, was the President and CEO of Cassava and Chairman of the Board until Barry took over as Executive Chairman of the Board and principal executive officer in July 2024. ¶¶194, 198. Barbier, and later Barry, were the primary spokespersons for Cassava. *See, e.g.*, ¶¶123, 130, 147,

¹⁹ *See Nathenson*, 267 F. 3d at 425 (company with 32-35 full-time employees “not large”).

159, 162, 168, 173 (public filings quoting, and statements made by, Barbier and Barry).²⁰ Prior to taking over Barbier’s role, Barry was a member of the Board that (i) engaged Orrick to conduct an internal investigation into the allegations of research misconduct and (ii) empowered the Ad Hoc Investigation Committee. ¶198. Burns was the Senior Vice President of Neuroscience until July 2024 and played a critical role in the development of simufilam, including as a co-inventor and collaborator with Dr. Wang on various journal articles and grant applications. ¶197. As CFO, Schoen was responsible for assessing the potential financial impact of the ongoing investigations into research misconduct as well as any settlements. ¶196. Barbier, Barry, and Schoen also signed off on critical misstatements. *See* ¶¶123, 125, 127, 129-30, 132, 135, 144-47, 159-60, 162-64, 166, 168, 175. These circumstances all contribute to an inference of scienter.²¹

III. THE AC ADEQUATELY ALLEGES LOSS CAUSATION.

To support loss causation based on corrective disclosures, the AC need only allege “a facially plausible causal relationship between the fraudulent statements . . . and plaintiff’s economic loss,” by alleging material misstatements “followed by the leaking out of relevant or related truth about the fraud that caused . . . the stock [drop] and plaintiff’s economic loss.” *Lormand*, 565 F.3d at 258. Rule 8’s notice pleading standard applies. *Id.* at 255. The standard for when alleged corrective information is “related to” or “relevant to” prior misstatements “is not a steep or difficult one to satisfy.” *Public Emps.’ Ret. Sys. of Miss. v. Amedisys*, 769 F.3d 313, 321-

²⁰ *See Plumbers & Pipefitters Loc. Union No. 630 Pension-Annuity Tr. Fund v. Arbitron Inc.*, 741 F. Supp. 2d 474, 491 (S.D.N.Y. 2010) (inference of scienter “strengthened” by the defendant being “the primary person who spoke about” the issue publicly).

²¹ Defendants’ authority, *Arthrocare*, 726 F. Supp. 2d at 719-20 (Br. at 22-23), is inapposite because, unlike here, the plaintiff simply alleged because the CEO and CFO were “involved in running the company,” they “must have known what was going on.”

22 (5th Cir. 2014).²²

Here, the AC easily meets that standard. The truth about the alleged research misconduct, related government investigations, tainted Phase 2b Study, and the reasons behind Barbier’s and Burns’ departures emerged over time, causing Cassava’s stock to decline. ¶237. On June 28, 2024, the truth about the alleged research misconduct and related government investigations began to trickle out when the DOJ announced that Dr. Wang had been indicted for falsifying data to obtain grants, after which Cassava’s stock declined over 34%. ¶¶137-39. Cassava’s stock price declined even further the following trading day when Cassava further revealed the DOJ and SEC had been investigating Cassava and two senior employees, and Cassava’s internal investigation identified that a senior employee had emailed Dr. Wang sufficient information to unblind himself. ¶¶140-42. Analysts reacted negatively. ¶¶241-42. More facts about the alleged research misconduct, related investigations and unreliable Phase 2b Study trickled out on August 8, 2024, when Defendants revealed that Cassava was in “advanced stages of discussions” with the SEC to resolve its nearly three-year investigation and investors should not place “undue reliance” on the Phase 2b Study results because, *inter alia*, Dr. Wang could have been unblinded. ¶¶149-50. Cassava’s stock declined about 13.84% thereafter. ¶243. The truth that Barbier and Burns were the senior employees implicated, Burns was to blame for Dr. Wang’s possible unblinding, and Burns and Barbier were subject to officer-and-director bars pursuant to their settlement with the SEC emerged on September 26, 2024. ¶¶153-56. The following day, Cassava’s stock price declined 10.61%. ¶157. These allegations adequately support loss causation. *Amedisys*, 769 F.3d at 326 (“specific allegations of . . . partial corrective disclosures” and allegations of “subsequent fall in Amedisys

²² *Amedisys* cited the Company Defendants’ authority, *FindWhat Iv’r Grp. v. FindWhat.com*, 658 F.3d 1282 (11th Cir. 2011), as consistent. *Amedisys*, 769 F.3d at 322. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005), likewise acknowledged the low burden.

stock value” adequately alleges loss causation); *Rougier*, 2019 WL 6111516, at *13 (loss causation adequately pled where “partial corrective disclosures support[ed] an inference that Defendants’ misstatements and omissions concealed the circumstances that b[ore] upon the loss and that the partial corrective disclosures were closely followed by a fall in AOI’s stock price”).

While the Company Defendants argue these disclosures were not corrective, their own authority supports that “a disclosure need not precisely mirror an earlier misrepresentation.” *Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 230 (5th Cir. 2009). *See also Del. Cnty. Emps. Ret. Sys. v. Cabot Oil & Gas Corp.*, 620 F. Supp. 3d 603, 634 (S.D. Tex. 2022) (“A corrective disclosure need not be a direct admission that a prior statement was false.”).²³ They also argue the disclosures about the Phase 3 trials were not corrective (Br. at 24-25), but as discussed in Plaintiffs’ Opposition to Burns’ and Barbier’s motion §III.B, the AC adequately alleges that those revelations were materializations of an undisclosed risk. Finally, their unsupported argument (Br. at 25 n.9) that the market reacted positively when the final Phase 2 Study results were published illogically²⁴ assumes the stock rose based on news about a prior study, when the drug that had already failed the later Phase 3 study, rather than in line with the market (¶¶180-81).

CONCLUSION

For the foregoing reasons, and for the reasons discussed and incorporated herein by reference in Plaintiffs’ Opposition to Barbier’s and Burns’ motion to dismiss, the Court should deny the Company Defendants’ motion in its entirety.

Dated: December 22, 2025

Respectfully submitted,

/s/ Murielle J. Steven Walsh
Murielle J. Steven Walsh (*pro hac vice*)

²³ The Company Defendants’ literal truth argument (Br. at 24) fails. *See supra* Section 1.A.

²⁴ The Court should not entertain this “cursory argument[] raised only in [a] footnote[.]” *Sable Networks, Inc. v. Cloudflare, Inc.*, 2024 WL 718690, at *2 (W.D. Tex. Feb. 5, 2024).

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CERTIFICATE OF SERVICE

I, Murielle J. Steven Walsh, hereby certify that on December 22, 2025, the foregoing was served upon each attorney of record through the Court's CM/ECF system.

/s/ Murielle J. Steven Walsh
Murielle J. Steven Walsh (*pro hac vice*)